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8 UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
9 AT TACOMA

10 UNITED STATES OF AMERICA,
11

12 Plaintiff,

13 v.

14 RICHARD MARSCHALL,
15

Defendant.

CASE NO. 3:20-cr-05270-RJB

ORDER DENYING DEFENDANT'S
MOTIONS TO DISMISS

16 This matter comes before the Court on Defendant's Motion to Dismiss on First
17 Amendment Grounds (Dkt. 44), Motion to Dismiss (Dkt. 45), and Motion to Dismiss for Failure
18 to State an Essential Element (Dkt. 76). The Court heard oral argument on December 21, 2020,
19 and has considered the pleadings filed in support of and in opposition to the motions and the file
20 herein.

21 **I. BACKGROUND**

22 **A. FACTS**

23 Defendant, Richard Marschall, is charged with the introduction of a misbranded drug into
24 interstate commerce in violation of 21 U.S.C. §§ 331(a) and 333(a)(2). The alleged drugs at

1 issue are products Mr. Marshall called the “Dynamic Duo.” Dkt. 38. The Dynamic Duo is
 2 comprised of Allimax® Pro (Allimed), which is a derivative of garlic, and IAM™
 3 Arabinogalactans, a derivative of larch tree. Dkt. 44 at 9. The indictment alleges that the
 4 Dynamic Duo was misbranded in four ways:

- 5 a) the labeling was false and misleading in some particular, in violation of 21 U.S.C. §
 6 352(a), in that it suggested that RICHARD MARSCHALL was a naturopathic doctor
 by listing him as “Rick Marschall N.D.”;
- 7 b) the drugs were prescription drugs pursuant to 21 U.S.C. § 353(b)(1), because the
 8 drugs’ method of use, and the collateral means necessary for their use, rendered them
 not safe for use except under the supervision of a licensed practitioner, and the drugs
 were dispensed without a prescription in violation of 21 U.S.C. § 353(b)(1);
- 9 c) the labeling failed to bear adequate directions for use as required by 21 U.S.C. §
 10 352(f)(1), because the drugs were prescription drugs pursuant to 21 U.S.C. §
 353(b)(1), because the drugs’ method of use, and the collateral means necessary for
 their use, rendered them not safe for use except under the supervision of a licensed
 practitioner; and
- 11 d) the drugs were manufactured, prepared, propagated, compounded and processed in
 12 establishments not registered with the Food and Drug Administration, and the drugs
 were not included in any list of drugs manufactured, prepared, propagated,
 13 compounded, and processed in a registered establishment, as required by 21 U.S.C.
 §§ 352(o), 360(b), 360(c), and 360(j).

14 Dkt. 38 at 5–6.

15 Also at issue, but not in the indictment, are statements allegedly made by Mr. Marschall
 16 about the ability of the Dynamic Duo to cure or treat diseases including COVID-19. *See* Dkt. 1
 17 at 7 (“Allimed and I.A.G. ‘can crush 30 different viral infections, including those in the Corona
 18 family, (like in China Corona-19), 40 different bacterial infections, 25 different fungal infections
 19 and 20 different parasitic infections like amoebas.’”).

20 **B. PENDING MOTIONS**

21 Defendant raises three pending motions to dismiss. First, on the grounds that the charges
 22 against Defendant violate the First Amendment. Second, that the products at issue are not
 23 “drugs” but are “dietary supplements” and, therefore, are regulated by a different statute than the
 24 one charged. Third, that the indictment fails to allege a necessary *mens rea* element of intent.

II. DISCUSSION

A. MOTION TO DISMISS ON FIRST AMENDMENT GROUNDS

Defendant moves to dismiss the indictment on the grounds that 21 U.S.C. § 331(a) unconstitutionally regulates speech in violation of the First Amendment both facially and as-applied. Dkt. 44.

21 U.S.C. § 331(a) prohibits “[t]he introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded.” Under 21 U.S.C. § 321(g)(1)(B), a “drug” means “articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animal.”

The speech at issue includes statements made about Defendant’s product, the “Dynamic Duo,” and its ability to “crush 30 different viral infections, including those in the Corona family, (like in China Corona-19), 40 different bacterial infections, 25 different fungal infections and 20 different parasitic infections like amoebas.” Dkt. 1.

Section 331(a) regulates the conduct of selling a drug in interstate commerce. The government seeks to use the speech at issue as evidence that Defendant intended the Dynamic Duo “for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man,” which is required to show that the products meet the definition of a drug under § 321(g)(1)(B). In short, the statute regulates conduct, and the challenged speech is being used as evidence of that prohibited conduct. Accordingly, § 331(a) is not unconstitutional in this context either facially or as-applied.

Defendant’s motion to dismiss on First Amendment grounds (Dkt. 44) should be denied.

B. MOTION TO DISMISS BASED ON DEFINITION OF A “DRUG”

Defendant also moves dismiss based on the argument that the substances at issue are supplements, not drugs.

The definition of both a “drug” under 21 U.S.C. § 321(g)(1)(B) and of a “dietary supplement” under 21 U.S.C. § 321(ff) depends on the substance’s intended use. For example, a “dietary supplement” “means a product (other than tobacco) intended to supplement the diet[.]” 21 U.S.C. § 321(ff)(1). The statute also states, “[e]xcept for purposes of paragraph (g) . . . a dietary supplement shall be deemed to be a food within the meaning of this chapter.” 21 U.S.C. § 321(ff). Paragraph (g) refers to 21 U.S.C. § 321(g), which defines “drug,” as discussed above, as “articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animal.” (emphasis added). The statute contemplates the same product being deemed either a food or a drug depending on its intended use.

Because use of a product as a dietary supplement does not prohibit that same product from being regulated as a drug depending on its intended use, Defendant’s motion to dismiss (Dkt. 45) should be denied.

C. MOTION TO DISMISS FOR FAILURE TO STATE AN ESSENTIAL ELEMENT

Finally, Defendant moves to dismiss the indictment for failure to state an essential element. Defendant argues that the government fails to allege the *mens rea* requirement that “[he] *intentionally* and *knowingly* introduced, delivered, and caused the introduction and delivery for introduction into interstate commerce misbranded drugs in violation of 21 U.S.C. §§ 331(a) and 333(a)(2). Dkt. 76 at 1.

Section 331(a) prohibits “[t]he introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or

1 misbranded.” The plain language of the statute does not require the government to allege that
2 Defendant intended the Dynamic Duo as drugs. The indictment alleges that Defendant “caused
3 to be introduced and delivered for introduction into interstate commerce . . . drugs . . . which
4 were misbranded[.]” Dkt. 38. The indictment identifies the products at issue as the “Dynamic
5 Duo” of Allimax® Pro (Allimed) and IAM™ Arabinogalactans, and states four ways in which
6 they were allegedly misbranded. *Id.* While the government may be required to prove at trial that
7 the products at issue meet the definition as a “drug” as defined in § 321(g), discussed above, the
8 indictment sufficiently alleges that Defendant violated § 331(a) and should not be dismissed.

9 Defendant also references the intent requirement in § 333(a)(2). Dkt. 76 at 3. Section
10 333(a)(2), which regulates penalties for violation of § 331, states: “. . . if any person commits
11 such a violation after a conviction of him under this section has become final, or commits such a
12 violation with the intent to defraud or mislead, such person shall be imprisoned for not more than
13 three years or fined not more than \$10,000, or both.”

14 While § 333(a)(2) does include the *mens rea* requirement of “intent to defraud or
15 mislead” for first-time offenders, it does not include any such scienter for defendants with
16 previous final convictions under that section. The indictment alleges that Defendant was twice
17 previously convicted under §§ 331(a) and 333(a)(2). Dkt. 38 at 4. The indictment, therefore,
18 states the essential element that the Defendant has previously been convicted under that section
19 and need not also allege intent to defraud or mislead.

20 Defendant’s motion to dismiss (Dkt. 76) should be denied.


21 **III. ORDER**

22 Therefore, it is hereby **ORDERED** that:

- 23 • Defendant’s motions to dismiss (Dkts. 44, 45, and 76) **ARE DENIED.**

1 The Clerk is directed to send uncertified copies of this Order to all counsel of record and
2 to any party appearing *pro se* at said party's last known address.

3 Dated this 22nd day of December, 2020.

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5 ROBERT J. BRYAN
6 United States District Judge
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